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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/116,676	07/16/1998	NIKA ADHAM	53801/JPW/KD	2822

7590 05/30/2002
JOHN P WHITE
COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/30/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/116,676

Applicant(s)

ADHAM

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 209,214,218-220 and 222-228 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 209, 214, 218-220 and 224-228 is/are allowed.
- 6) ☒ Claim(s) 222 and 223 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 209, 214, 218-220 and 222-228 are pending in the instant application. Claims 222, 224, 226 and 228 have been amended and claims 1-9, 14-48, 150, 208 and 213 have been canceled as requested by Applicant in Paper Number 18, filed March 12, 2002.

Withdrawn Objections and Rejections

- 2.1 The objections to the claims are withdrawn in view of Applicants' amendment.
- 2.2 The rejections of claims under 112 § 2 are withdrawn in view of Applicants' amendment.
- 2.3 The rejection of claims under 35 USC § 102 is withdrawn in view of Applicants' amendment.
- 2.4 The rejection of claims under 35 USC § 103 is withdrawn in view of Applicants' amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3.1 Claims 222 and 223 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the Previous Office Action, Paper No. 17, page 3, section 5.1.

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Applicants traverse the rejection and submit the definitions of analog and homolog recited in Dorland's Illustrated Medical Dictionary, 24th Edition, 1965, and note that claim 223 does not recite "homolog" or "analog". Applicants maintain that a radiolabeled homolog and analog of a compound that binds hOb-Re, i.e. [¹²⁵I] leptin, is disclosed in the specification on page 17, line 23 through page 18, line 36. Applicants further maintain that leptin homologs and analogs were well-known in the art at the time the application was filed, and that one skilled in the art would know what a structural and functional homolog or analog of such a compound would be due to the many examples of such compounds available to the skilled artisan at the time the application was filed.

Applicants' arguments have been fully considered but are not deemed persuasive. First, although claim 223 does not recite "homolog" or "analog", these terms are encompassed in the claim because claim 223 depends from claim 222. Second, although the terms "homolog" or "analog" were well known in the art, it is not disclosed what such a compound would look like. Applicants point to [¹²⁵I] leptin as a radiolabeled homolog and analog of a compound that binds hOb-Re. However, this compound also binds to the hOb-Re receptor, and so would not be characterized as a homolog or analog, since the claims as written encompass a compound that binds to the receptor *or* a structural and functional analog or homolog thereof. As the claims are written, the structural and functional analog or homolog would not bind the receptor, and the specification has not adequately disclosed such compounds, nor taught how to use compounds that would not bind.

3.2 Claims 222 and 223 also remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are rejected for reciting the step “wherein said chemical compound has been recovered free of any soluble polypeptide”.

Applicants have amended claim 223 so that step (b) recites “recovering said chemical compound free of any soluble polypeptide”, and maintain that the “recovery step” is supported in the specification on pages 66, 68 and 69 in assays in which the reaction mixture is filtered or separated, thus recovering the compound free of any receptor.

Applicants’ arguments have been fully considered but are not deemed persuasive. In the assays on page 66 for example, membrane preparations are incubated with various compounds that are labeled, and it is the unlabeled ligands that are separated away, leaving the compound that binds to the receptor in the membrane still bound to the membrane. Though soluble polypeptides may be removed, the compound is bound to the membrane, and this is not the method that is encompassed by the claim. Though this and other assays have some type of filtration or separation step, the steps and goals are different from that of claim 222. The recovery step is not necessary, and the rejection would be withdrawn if step (b) in claim 222 were deleted.

It is believed that all pertinent arguments have been answered.

Conclusion

4.1 Claims 209, 214, 218-220 and 224-228 are allowed.

4.2 Claims 222 and 223 are rejected. Claims 222 and 223 would be allowable if claim 222 were amended to delete “or a structural and functional analog or homolog thereof” and step (b).

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

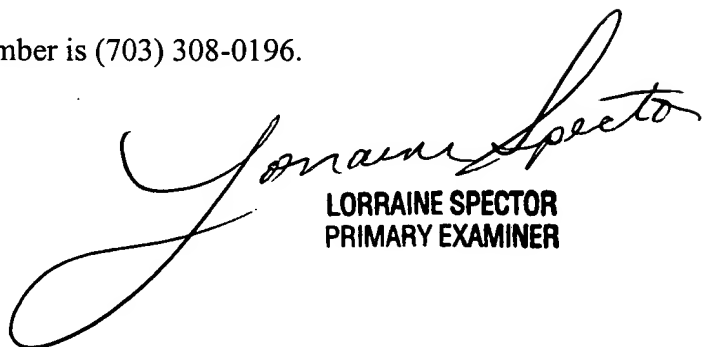
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner


LORRAINE SPECTOR
PRIMARY EXAMINER